

## Introduction

1. The Human Tissue Authority (HTA) welcomes the opportunity to respond to the Health and Social Care Committee's consultation on the Draft Human Transplantation (Wales) Bill (the Bill).
2. As the statutory regulator responsible for the consent provisions within the Human Tissue Act 2004 (HT Act), the HTA is charged with ensuring that appropriate and valid consent is in place when organs and tissue are donated from deceased and living people for the purpose of transplantation.
3. The HT Act covers England, Wales and Northern Ireland and requires consent for a number of activities, including organ donation, to be an active and positive act.
4. There are similar provisions in Scotland under the Human Tissue (Scotland) Act 2006 (HT (Scotland) Act), and while the word "authorisation" is used in place of "consent", there is a requirement that this is a positive act and the principle is the same.
5. This response is in regard to the Welsh Government's proposal to introduce an opt-out system for organ donation in Wales. The essence of the proposal is that, for people who both live and die in Wales and who did not make a decision in life on organ donation, the presumption will be that they wished to donate their organs and tissue after death.
6. The HTA has responded to previous consultations on the introduction of an opt-out system for organ donation. These responses can be found [here](#).

## The proposal

7. It is of value to set out the main features of the Welsh Government's proposals in order to place this response in context.
8. The Bill introduces the concepts of deemed and express consent. Express consent is identical to the active consent requirement of the HT Act. It is, in the first instance, the consent of the person themselves in life. If that does not exist, the consent of an appointed representative, and, if there is not a representative, then the consent of a person in a qualifying relationship to the donor.
9. Under the Bill express consent will be required for:
  - a. Living organ donation
  - b. Deceased organ donations from children
  - c. Deceased organ donations from adults who lack the capacity to consent
  - d. Deceased donations from people who live and die in Wales but have not been resident for six months or more
  - e. Deceased organ donations from people who die in Wales but who are not resident in Wales
  - f. Deceased organ donations from Welsh residents who die somewhere else in the UK
10. Under the Bill, when an adult Welsh resident who had the capacity to consent dies in Wales, and had registered either a wish to be considered as an organ donor, or their wish not to be an organ donor, this will be acted upon, if possible.
11. If such a person has not registered either a yes or a no, then their consent will be deemed. This means that the starting point of the conversations which will be held with the potential donor's family and friends is that they wished to donate. At present, when there is no recorded wish the family are approached to ask whether they are aware of the wishes of the deceased.
12. The fact that the family will still be involved in the process under the Welsh Government's proposals means that this key safeguard remains in place. Although the family will not have the right to veto the donation if a recorded yes is in place or consent is deemed, if they are able to provide evidence that would satisfy a reasonable person that the deceased did not wish to be a donor this will be accepted.

13. If a person has recorded a no, their family will be informed of this. If a document signed by the deceased, and which post-dates the recorded decision to opt-out, is presented by the family, then donation might be considered.
14. It should be noted that the current legislation (the HT Act) does not give families a veto over the deceased's recorded wishes. When a person has registered on the Organ Donor Register (ODR), and subsequently dies, the role of the family is to let the Specialist Nurse for Organ Donation (SNOD) know whether they had changed their mind, and to provide the medical and lifestyle information necessary to carry out the risk assessment which is required for a decision to be made on whether donation should go ahead. The existing legislation does not make provision for a family to stop a donation because they do not want it to go ahead.
15. In reality, however, the duty of care the surgical and medical teams have to the family of the deceased means that a donation will not usually proceed without their support. This matter is coming to the fore in discussions on deceased donation rates across the UK. The HTA has engaged and will continue to follow with interest these discussions.
16. The HTA believes that there are areas which require further consideration prior to the implementation of the proposed system. However, the operational process as laid out in the explanatory memorandum does not differ significantly from that which operates at present, in the sense that the register will be consulted and a conversation will then be held with the family.
17. What will change is that there will be a new register which will record both wishes to donate and wishes not to donate, and that where the deceased had not made a decision in life, their family will be approached on the basis that he/she wished to be a donor.

## **The role of the HTA**

18. As a statutory regulator, it is not the role of the HTA to either support or object to the proposals of the Welsh Government, which is constituted of the elected representatives of the Welsh people.
19. It is the role of the HTA to provide advice and guidance as required, and this document seeks to provide a detailed response to the areas highlighted in the Committee's letter of 6 December 2012 and other issues for consideration by the Committee. This advice and guidance is based on the experience the HTA has gained since it was established in 2005, and on the provisions of the HT Act as it currently stands.
20. The HTA notes the ethical discussions on the Welsh Government's proposals. However, as a statutory regulator it is outside the remit of the HTA itself to participate directly in such discussions.

## **Response to terms of reference of the inquiry**

21. In its letter of 6 December 2012 the Committee outlined the terms of reference for the inquiry and the HTA has addressed those within its remit below.

### ***The individual provisions set out in the Bill:***

#### ***Section 2, relating to the promotion of transplantation***

22. The HTA has no comments in regard to section 2 of the Bill.

#### ***Section 3, relating to lawful transplantation activities***

##### ***Licensing***

23. Under the HT Act a licence is required for two of the activities listed in section 3. These both relate to storage and are included at s.3(2)(a) and (c) of the Bill.

24. The HT Act requires consent (as laid out in section one of the HT Act) for each of these storage activities and as such a licensed establishment must demonstrate that consent is in place as part of the HTA's licensing requirements.

25. Under the Quality and Safety of Organs Intended for Transplantation Regulations 2012 a licence is required for the removal or implantation of an organ. A licence granted by the HTA under these Regulations also requires that HT Act consent is in place.

26. The Welsh Government and the Department of Health will need to ensure that between the three pieces of legislation the licensing requirements for these activities are unaffected by the move to deemed consent in Wales.

##### ***Relevant material***

27. There is value in noting that section 3 of the Bill refers to "relevant material" rather than just organs. Relevant material is defined at section 16 of the Bill and means "material, other than gametes, which consists of or includes human cells". Relevant material does not include "embryos outside the human body" or "hair and nails from the body of a living person".

28. At present the Welsh Government's plans in regard to deemed consent only address solid organs. However, the Bill provides scope for the transplantation of any relevant material to be lawful with deemed consent. This means that there would be no need for the legislative process to be undertaken to introduce deemed consent to the transplantation of other relevant material.

### ***Import and export***

29. Under section 41 of the HT Act the following definitions for import and export are provided:

- a. "Import" means import into England, Wales or Northern Ireland from a place outside England, Wales or Northern Ireland.
- b. "Export" means export from England, Wales or Northern Ireland to a place outside England, Wales or Northern Ireland.

30. Section 3 of the Bill suggests that it is the intention of the Welsh Government that the definitions at section 41 of the HT Act will no longer remain, and in fact, relevant material of the kind mentioned in s.3(2)(c) or (d) will be considered imported if it originates from any jurisdiction outside Wales.

31. If this is the intention, it will be of vital importance for the Welsh Government and NHS Blood and Transplant (NHSBT) to work together to remedy any impact this would have on the allocation and use of deceased donor organs across the UK.

32. Amendments may be required to the HT Act to ensure consistency between this and the Welsh legislation.

33. It will also be important that there is clear and timely communication that the consent requirements of the HT Act in regard to removal of material for the purpose of transplantation remain in place in England and Northern Ireland, and likewise for the HT (Scotland) Act in Scotland.

### ***Section 4-8, relating to consent***

#### ***Registration of wishes***

34. The HTA notes the information provided in the Explanatory Memorandum and Privacy Impact Assessment on the proposed system by which Welsh residents will be able to register their wishes.

35. The HTA further notes that specifying such a system in primary legislation would restrict any changes or amendments that are required to the system in the future. However, without firm assurances as to the system which will be introduced to allow Welsh residents to register their wishes. It is difficult to assess how the process of establishing or seeking consent will differ from that which currently exists.
36. Establishing whether consent is in place and seeking of consent are complex matters and involve communication with people in a period of high emotion. It will be key that any move to a system of deemed consent does not add further complexity and that everyone involved in the process, including clinicians and the family, are informed fully of their role and responsibilities.
37. The HTA believes that the Welsh Government's proposal of a register which allows Welsh residents to both opt-in and opt-out of organ donation is fundamental to guarantee that the wishes of the deceased in life remain paramount. This must be both easy to access and readily available.
38. Such a register would allow the HTA to have greater confidence when drafting a Code of Practice including guidance on deemed consent in Wales, as the practical issues could be clearly addressed and advice provided on what steps should be taken in given circumstances.
39. The absence of such a register could, in the view of the HTA, increase confusion and uncertainty on the proposed system, and could lead to the provision of advice and guidance by any organisation (including the HTA) being unclear and unhelpful.

### ***Living organ donation***

40. Under the provisions of the Bill, consent for living organ donation remains "express", in that it is the consent of the individual. In practice it is difficult to imagine when consent to living organ donation could ever be anything other than express, although it should be noted that provision is made in both the Regulations<sup>1</sup> supporting the HT Act and the Bill for living donors who are children or adults who lack the capacity to consent.
41. It is unclear to the HTA why living organ donation is included in the Bill, and on the face of it this inclusion adds complexity and confusion to no identifiable end.

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<sup>1</sup> <http://www.legislation.gov.uk/ukxi/2006/1659/contents/made>

***Section 9-11, relating to offences***

42. Under section 11, consideration should be given to being specific as to who should make a referral to the Director of Public Prosecutions.
43. From the HTA's experience there is merit in policies and procedures being in place from an early stage in order that all involved understand their responsibilities when an offence may have been committed. The Welsh Government may choose not to include this level of detail in the primary legislation; however, it should be available in good time for the proposed 2015 launch date.

***Sections 12-20, which make general provision***

44. Section 15(6)(b) of the Bill reads "after subsection (6) insert -", the HTA believes this should read "after subsection (5) insert-".

***Any potential barriers to the implementation of these provisions and whether the Bills takes account of them***

45. Once it becomes law, the Bill will place a number of explicit and implied duties on the Human Tissue Authority. In addition to the requirement to produce a Code of Practice, the HTA is also placed under a duty to superintend the Act. We understand this to mean the provision of advice and guidance on how the legislation should be interpreted.
46. While the HTA has not yet had the opportunity to undertake a full analysis of the impact of the Bill, an initial assessment has identified a number of possible risks to the implementation of the provisions from a regulatory perspective. These relate to our role in advising on the practical circumstances under which consent can be deemed.
47. The HTA currently provides advice on the conditions which need to be fulfilled for consent to be valid. One of these conditions, that consent should be active, will be removed, under certain circumstances, in Wales as a result of the Bill.
48. A further condition is that consent should be informed. It appears to us that for deemed consent to have legitimacy; people affected by it must clearly understand the circumstances under which their consent will be deemed. The explanatory memorandum sets out the communication activity that will support the policy and we provide more detailed views on this in paragraphs 63 to 69. It is the Authority's view that widespread understanding among



people living in Wales, over time, is a pre-requisite to being able to advise on specific circumstances under which consent can be deemed. By extension, any reduction in this understanding may limit our ability to provide such advice.

49. Considering the specific provisions of the Bill, section 4 sets out consent provisions for adults. It states that consent can be deemed where express consent is not present. One of the tests for express consent is “the person has died, and a decision of the person to consent or not to consent to the activity was in force immediately before his or her death”.
50. The explanatory memoranda make clear that the intention is to have a register in Wales which records wishes to opt-in or opt-out. While we believe this is necessary, it will not necessarily be sufficient as a basis for establishing the wishes of the individual in life. That is to say that the register will not, in law, be the sole mechanism by which wishes could be registered. A person could opt-out orally or in writing in a variety of ways. For example, registering a desire to opt-out in a will appears to us to be legitimate. Alternatively, if the family said that the deceased had orally expressed the desire not to donate, this also seems to us legitimate.
51. While express consent to donate might not be identified under the current system (resulting in no donation going ahead), the consequences of failing to identify an express wish not to donate under a system of deemed consent (and the donation proceeding) seem to be of a different magnitude ethically and legally. As a result we would expect to take a range of stakeholder views on the appropriate checks to undertake in order to reflect these in a Code of Practice.
52. While our experience (in partnership with NHS Blood and Transplant) will allow us to develop a Code of Practice, a system so designed may pose a number of operational challenges. We are working with officials in Wales and colleagues in NHSBT to address these issues.

***Whether there are any unintended consequences arising from the Bill***

53. The HTA has sought to address potential unintended consequences in relation to the sections of the Bill above.
54. In particular, please note paragraphs 23 to 26 above on licensing.
55. More generally, the HTA would further advise that agreed review periods are built into the post-launch programme to allow an assessment of the impact of

the legislation. If the impact is a drop in the number of organs being donated, steps should be taken rapidly to understand the root causes.

56. Negative coverage of deemed consent in Wales could lead to mistrust in other parts of the UK, and it will be vital that this change does not adversely impact organ donation.

***The financial implications of the Bill (as set out in Part 2 of the Explanatory Memorandum (the Regulatory Impact assessment), which estimates the costs and benefits of the implementation of the Bill)***

57. The table of fixed costs associated with the adoption of the opt-out system on page 45 of the Explanatory Memorandum details that spending on communications will fall in the period 2017-22 to £50k per annum, from a high of £1.453m in 2015-16.
58. The HTA believes that communication will be vital in ensuring the legitimacy of a system of deemed consent, in the sense that without it Welsh residents will not know what action they are required to take in order not have their consent deemed, and would caution that £50k per annum appears to be a low spend for such a vital issue.
59. As noted in previous HTA response documents on this matter, a new group of people will be impacted by the system year-on-year and while steps should have been taken during the implementation and launch phases to raise general awareness, campaigns will be required every year. It is true that in order to maintain the legitimacy of a system of deemed consent there will need to be a continuous communication programme, so those that have made a decision in the past are able to revisit it if they wish.
60. The HTA also questions whether an overall communications spend of £2.9m over ten years is adequate for such a significant legislative and operational change on a sensitive and complex issue.

***The appropriateness of the powers in the Bill for Welsh Ministers to make subordinate legislation (as set out in part 1, paragraph 90 of the Explanatory Memorandum, which contains a table summarising the powers for Welsh Ministers to make subordinate legislation)***

61. The HTA is not in a position to comment on the appropriateness of the powers in the Bill for Welsh Ministers to make subordinate legislation.

## **Areas for further consideration**

62. The HTA would highlight the following three areas as those which require further consideration and development, and which will be key to the effective implementation and operation of the proposed system.

### *Communications*

63. The commitment made in the Explanatory Memorandum to an effective and sustained communications campaign is noted by the HTA. Communication will be vital in ensuring that every person living in Wales and the bordering counties is aware of the proposed system and how it will affect them. In order for the individual's decision to remain paramount they must be aware of the action they are required to take, if any, to make their views known.

64. Communication with all Welsh residents and those living in the border counties will be important, and attention should be given specifically to those groups who are regarded as being hard to reach. These include those people whose first language is not English or Welsh, and also those living in deprived areas.

65. It will be important to develop a communications plan which ensures people who move to Wales are made aware of the system soon after they become resident, in order to allow them sufficient time to make a decision and, if necessary, record their wishes.

66. The HTA considers that the planned communication with every Welsh resident six months prior to their eighteenth birthday will be important to ensure that there is time for these young people to make an active decision prior to deemed consent applying to them.

67. Any risk of a particular group or groups of Welsh residents being left behind on this matter due to poor communication must be actively addressed by the Welsh Government. Without an effective, comprehensive, targeted and continued communications campaign the proposed system cannot be said to hold the decision of the individual in life as a core principle. Indeed, without proper communication an individual may not be in receipt of the information they require to know what their silence on the matter of organ donation after their death will be considered to mean.

68. In previous responses to the Welsh Government's consultations on an opt-out system for organ donation, the HTA has stressed the importance of a continuous communications campaign. Such a campaign will be critical in ensuring that every Welsh resident remains aware of whether or not the system affects them, and what action they need to take. If the focus on this continuous communications campaign is lost, then there is a significant risk that people will not be properly informed, leading to the whole system being undermined.
69. The HTA intends to continue to work with the Welsh Government to provide input on the communications activity for the proposed system.

*Cross-border issues*

70. The HTA believes that there is still work to be done on the cross-border issues which arise from the proposed system.
71. The introduction of a register for Welsh residents which records both wishes to donate, and wishes not to donate, would mean that there would be two different registers operating across the UK. In Wales it is envisaged that an individual will be able to record a yes to all organs, a yes to some organs, or an outright no. In the rest of the UK an individual will be able to record a yes to all organs or a yes to some organs. They will not be able to register a no.
72. Operationally this poses challenges as, under the HT Act, it is the wishes of the individual immediately before they died which are held as primary. Therefore if these wishes are recorded on the Welsh register they should be acted on, no matter where the individual dies. This means that, for Welsh residents who die outside Wales, the SNOD will be required to check any Welsh register which exists and act on the recorded wishes, if there are any. In fact, it would be prudent that any Welsh register is checked for every donor, as it may not be clear if they had ever been resident in Wales. By checking both registers the risk that the "wrong" information is relied upon is limited. Therefore, all SNODs must have access to any Welsh register and the Organ Donor Register and be in a position to easily establish whether a person is on either or both registers, and which record is most recent. This information will need to be quickly ascertained, most often in the middle of the night, and its accuracy must be guaranteed.
73. If individuals are able to record their wishes on the new Welsh register prior to implementation of the opt-out system, then this recording will in effect form the

last recorded wishes of the individual. It is vital that these are made available to SNODS in order to ensure compliance with the HT Act.

*Post-implementation review*

74. The consultation document commits to a thorough and on-going post implementation review and the HTA suggests that this seeks to highlight both successes and challenges. The HTA notes that both the Scottish Government and Northern Ireland Assembly<sup>2</sup> have expressed interest in the Welsh Government's proposals, and as such the post implementation review may form part of the basis of policy decisions in other parts of the UK. This unique opportunity to share the experience of one country of the UK with others should not be lost, and investigation of the true outcomes for all involved from donor families, to recipients and clinical staff will be key to the wider understanding of how such a system operates.

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<sup>2</sup> <http://www.eveningtimes.co.uk/news/bid-to-change-opt-out-laws-a-step-closer-112363n.19888806>  
and <http://www.bbc.co.uk/news/uk-northern-ireland-17089597>

## Summary

75. Since the Welsh Government announced their intention to introduce a system of deemed consent for organ and tissue donation in Wales, the HTA has been involved, to a varying degree, in the development of the Welsh Government's proposals which have resulted in the Bill which is the focus of this consultation.
76. The HTA is aware of the wide-range of views which exist on this matter, and as a statutory regulator has sought to provide advice and guidance on matters within its remit and on those areas in which the organisation has gained experience during the past eight years.
77. As detailed above, there are parts of the Bill which the HTA believes require further consideration and exploration.
78. However, it is those areas which are not specified in the Bill, for example the introduction of a Welsh register of people's wishes, the communications strategy and post-implementation review where assurances are needed to give confidence to all involved in the proposal.